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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,687	10/05/2000	Stephen M. Allen	BB1162 US NA	1467

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,687	ALLEN ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-30,32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25-30,32 and 34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location and the examiner of your application in the PTO have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Zachary C. Howard, Art Unit 1646, Technology 1600.

Status of Application, Amendments and/or Claims

The amendment of 6/6/05 and the supplemental amendment of 8/5/05 have been entered in full. Claim 32 is twice amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25-30, 32 and 34 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

The rejection of claim 32 under 35 U.S.C. § 101 at pg 2 of the 2/4/05 Office Action for being directed to non-statutory subject matter is *withdrawn* in response to Applicants' persuasive arguments at pg 4 of the 8/5/05 response. Claim 32 requires that that the cell comprises a recombinant DNA construct, clearly indicating the "hand of man" and distinguishing the claimed cell from a product of nature.

Claim Rejections - 35 USC § 101, utility

Claims 25-30, 32 and 34 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial utility or a well-established utility. This rejection was set forth at pg 2-4 of the 2/4/2005 Office Action.

Applicants' arguments (presented in the 6/6/05 amendment and duplicated for convenience in the 8/5/05 supplemental response) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicants submit at pg 5-6 of the 8/8/05 response that the issue of substrate variability is irrelevant because the claims require that the encoded polypeptide have sucrose transport activity, and therefore transporters lacking sucrose transport activity are outside the scope of the claims. Applicants further submit that the references of Bisson and Liang are not appropriate to cite as state of the art, because they drawn to, respectively, sugar transporters in a broad sense or glucose transporters, and are therefore removed from the subject matter of the instant invention, a sucrose transporter. Applicants assert that the Office Action applies an improperly broad classification to argue that the claimed invention lacks utility due to its differences from remotely related species. Applicants submit that Lemoine (2000) teaches that plant sucrose transport genes are thought to encode a protein containing two sets of six membrane spanning regions and further teaches twelve plant sucrose transporters that share conserved residues. Applicants submit an alignment of instant maize SEQ ID NO: 2 with rice SEQ ID NO: 26 and Aoki (1999) maize sucrose transporter. Applicants submit that SEQ ID NO: 2 has 129 out of 135 conserved residues and all four conserved cysteine residues. Applicants submit that maize SEQ ID NO: 2 is 91.5% to the maize sucrose transporter identified by Aoki (1999), and 81.7% identical to the rice sucrose transporter *OsSUT1* (SEQ ID NO: 26). Applicants submit that one skilled in the art would have no reason to doubt that that the protein encoded by SEQ ID NO: 2 has sucrose transport activity.

Applicants' arguments have been fully considered but are not found persuasive. The issue of substrate variability is relevant to utility, because Applicants have not demonstrated that the encoded polypeptide actually has sucrose transport activity. While the claims are limited to polypeptides that have sucrose transport activity, this does not impart utility to the invention if in fact the encoded polypeptide does not have sucrose transport activity. The reference of Bisson is appropriate in so far as it provides general teachings regarding substrate variability in sugar transporter function, because sucrose transporters are a type of sugar transporter. Likewise, the reference of Liang is appropriate in so far as it provides teachings showing that single amino acid mutations can affect the substrate specificity of a glucose transporter, which is a sugar transporter.

However, the Examiner concedes that the teachings of Lemoine are more closely directed to the state of the art related to Applicants' claimed invention than those of Bisson or Liang. However, the teachings of Lemoine also support the Examiner's position that the claimed polypeptide does not have a specific or substantial utility. Lemoine teaches that all twelve of the known plant sucrose transporters each have 134 conserved amino acids (pg 255). While instant SEQ ID NO: 2 has 129 of these conserved residues, including 4 conserved cysteine residues, the fact that it is missing five conserved residues and that many sugar transporters can transport other sugars (see Lemoine, Table 2) would give one of skill in the art reason to doubt whether or not it was a sucrose transporter. Lemoine also teaches that it is routine in the art to determine whether or not a protein is a sucrose transporter by expressing the transporter in yeast and determining its affinity for sucrose (pg 251). However, even if it was demonstrated that SEQ ID NO: 2 is in fact a sucrose transporter, this would not provide the novel sucrose transporter with a specific and substantial utility. As stated in the previous Office Action, "identifying a nucleic acid molecule as encoding a sucrose transporter does not endow the nucleic acid molecule with a specific and substantial utility." The teachings of Lemoine also support this position. Despite the similarities in the twelve known plant sucrose transporters, Lemoine teaches that individual plant species have multiple sucrose transporters and little is known about their specific functions. Lemoine teaches "The existence of several sequences related to already known sucrose carriers in the Arabidopsis database indicate that a whole family of sucrose transporter genes is present in one single plant...The next challenge will be to unravel the exact function of the new genes and their role in the plant." Similarly, Aoki et al (2003, Plant Cell Physiol, 44(3): 223-232) reports that five different SUT sucrose transporters have been found in rice (pg 224) with different expression patterns for 4 out of 5 (pg 227). Aoki further reports that other researchers have found two SUT sucrose transporters in barley, each with a different expression pattern (pg 223). Aoki concludes "The differential expression patterns of the five *OsSUT* genes in rice plants observed in this work suggest that the SUT gene family has many roles in both source and sink tissues, and at different developmental stages. It would be helpful to produce and

analyse suppression/knock-out lines, in order to fully understand the physiological roles of the SUT gene family in rice plants. It is also noteworthy that in each tissue tested, at least four OsSUT genes are apparently expressed. This overlapping expression may imply diverse roles of the five OsSUT proteins in membrane-mediated sucrose transport processes or could represent expression in different cell types" (pg 230). The Examiner agrees that instant SEQ ID NO: 2 is 91.5% similar to a maize sucrose transporter taught by Aoki (1999). However, this does not demonstrate that instant SEQ ID NO: 2 encodes a protein that has sucrose transport function. And even if the encoded protein can transport sucrose, this would only indicate that maize has two different sucrose transporters, presumably with different biological functions. While Aoki (1999) teaches the expression pattern of the maize sucrose transporter identified therein, the expression pattern of instant SEQ ID NO: 2 has not been demonstrated. The expression pattern may or may not be the same for the two maize sucrose transporters.

Applicants further submit at pg 6-7 of the 8/5/05 response that the specification asserts that sucrose transporters have utility in controlling grain fill. Applicants submit that Scofield et al (2002) teaches that antisense suppression of the rice sucrose transporter gene *OsSUT1* leads to impaired grain filling. Applicants point out that *OsSUT1* (SEQ ID NO: 26) is 81.7% identical to instant SEQ ID NO: 2. Applicants further submit that Hirose et al (1999) earlier saw high expression of levels of rice OsSUT1 in panicles after heading and postulated it was involved in transport of sucrose into the filling grain. In conclusion, Applicants submit that an asserted utility for polypeptides having sucrose transport activity, such as use in grain filling and improving yield and quality is a specific, substantial and credible utility.

Applicants' arguments have been fully considered but are not found persuasive. The Examiner agrees with Applicants' characterization of the teachings of Scofield and Hirose. The Examiner agrees that Scofield (2002) shows that antisense suppression of the rice sucrose transporter gene, *OsSUT1*, leads to impaired grain filling. However, the teachings of Scofield and Hirose do not provide a specific and substantial utility for instant SEQ ID NO: 2. Rather, the teachings of Scofield demonstrate what is necessary in the art in order to conclude that a particular sucrose transporter can be used to

control grain filling. Applicants have not shown that antisense suppression of instant SEQ ID NO: 2 leads to impaired grain filling in maize. Furthermore, the similarity between *OsSUT1* and instant SEQ ID NO: 2 does not allow one of skill in the art to know that SEQ ID NO: 2 could be used to control grain filling. As described above, the physiological function of specific plant sucrose transporters is not well understood and multiple sucrose transporters are found in a single species of plant. Applicants have not shown where instant SEQ ID NO: 2 is expressed in the maize plant. It may be expressed in different tissues than *OsSUT1*. Even if the expression pattern in tissues of SEQ ID NO: 2 is similar to *OsSUT1*, it does not necessarily follow that antisense suppression of SEQ ID NO: 2 would lead to impaired grain filling. As taught by Aoki (2003) and described above, the art appreciates that sucrose transporter genes could be expressed in different cell types within the same tissue and therefore have different functions.

For these reasons, it is maintained that the claimed invention, instant SEQ ID NO: 2, is not supported by either a specific and substantial utility or a well-established utility.

Claim Rejections - 35 USC § 112, enablement

Claims 25-30, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. This rejection was set forth at pg 5 of the 2/4/05 Office Action.

Applicants' arguments (presented 6/6/05 and reiterated in the 8/5/05 supplemental response) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 8/5/05 Applicants note that the enablement rejection was made with respect to 'how to use' the invention in connection with the lack of utility rejection and therefore refer to their remarks with regard to utility.

Applicants' arguments have been fully considered but are not found persuasive. The rejection for lack of a specific and substantial asserted utility or a well established utility has been maintained for the reasons set forth above. Therefore, it is maintained that one of skill would not know how to use the claimed invention.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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